

AMENDMENTS

✓
Please cancel claims 6, 14, 17, 18, 21 and 22, without prejudice or disclaimer.

✓
Please add the following claims:

31. (New) A bioadhesive, progressive hydration pharmaceutical composition comprising:

testosterone,

polycarbophil,

and a water soluble polymer,

wherein said composition is formulated to progressively hydrate and to deliver said testosterone to the bloodstream of a mammal through a mucosal surface of the mammal.

32. (New) The composition of claim 31, wherein the water soluble polymer is carbomer 974P.

33. (New) A method of administering testosterone to a mammal, comprising delivery of said testosterone via a progressive hydration bioadhesive composition to a mucosal surface of said mammal, wherein said composition includes

(a) said testosterone,

(b) polycarbophil, and

(c) a water soluble polymer.

34. (New) The method of claim 33, wherein said water soluble polymer is carbomer 974P.

IN THE CLAIMS

In accordance with 37 CFR §1.121, please substitute for original claims 1, 10, 23, and 26, the following rewritten versions of the same claims, as amended. The changes are shown explicitly in the attached Appendix A "Version with Markings to Show Changes Made."

1. (Four times amended) A bioadhesive, controlled, sustained release progressive hydration pharmaceutical composition in the form of a tablet, comprising:

F2
an effective amount of an active ingredient that is a sex hormone,
a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer, and

a water soluble polymer,

wherein said composition is formulated in a dry state to deliver, upon administration of said tablet to a mucosal surface of a mammal, said active ingredient to the bloodstream of said mammal.

10. (Twice Amended) A method of delivering testosterone to a mammal, comprising administering said testosterone via a bioadhesive, progressive hydration composition through a mucosal surface of the mammal, wherein the composition comprises:

F3
a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer,

a water soluble polymer, and

said testosterone,

and wherein said method provides a blood serum concentration ration of testosterone to 5 α -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

F4 23. (Twice Amended) A bioadhesive, progressive hydration pharmaceutical composition comprising:

testosterone,
a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer,
and a water soluble polymer,

wherein said composition is formulated to progressively hydrate and to deliver a therapeutically effective amount of said testosterone to the bloodstream of a mammal through a mucosal surface of the mammal.

F5 26. (Amended) A bioadhesive, controlled, sustained release progressive hydration composition for delivering testosterone to the bloodstream of a mammal, comprising:

a bioadhesive, water insoluble, water swellaable cross-linked polycarboxylic polymer,
a water soluble polymer,
and testosterone,

wherein said composition is formulated to deliver said testosterone through a mucosal surface of the mammal, and to provide a blood serum concentration ratio of testosterone to 5 α -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

Note: A marked-up copy of amended claims 1, 10, 23, and 26 is included in Appendix A hereto.